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(54) **DEFLECTABLE GUIDE**

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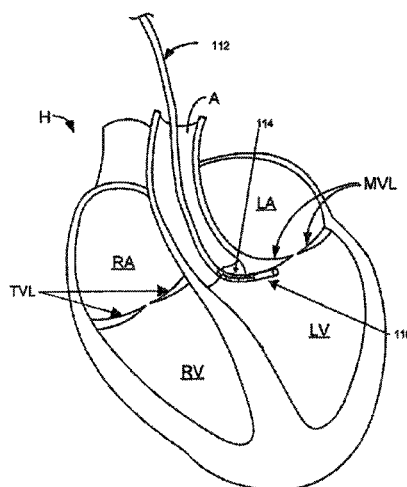
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(57)

ABSTRACT

Described herein are devices and methods for guide catheters having one or more regions of increased flexibility. A flexibility region comprises one tubular segment of the guide catheter with a non-linear seam between two non-concentric layers of material having different durometers. A non-linear seam, such as a zig-zag or sinusoidal configuration, permits controlled compression of lower durometer material between portions of higher durometer material.

21 Claims, 19 Drawing Sheets



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FIG. 1

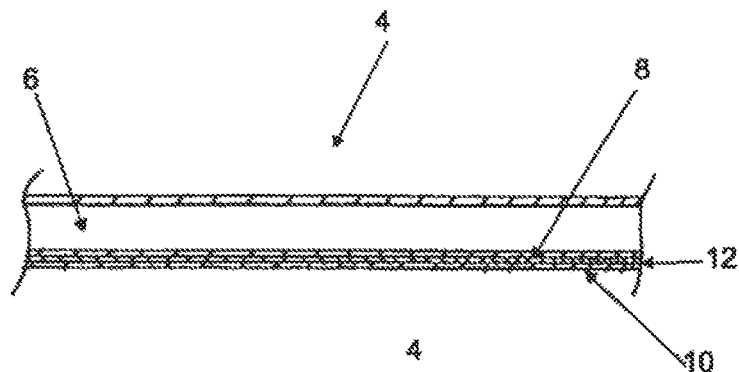


FIG. 2A

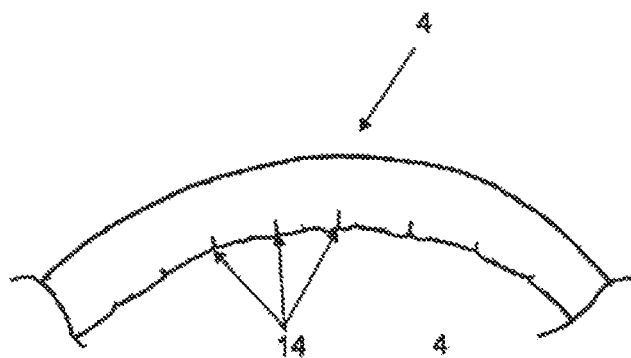
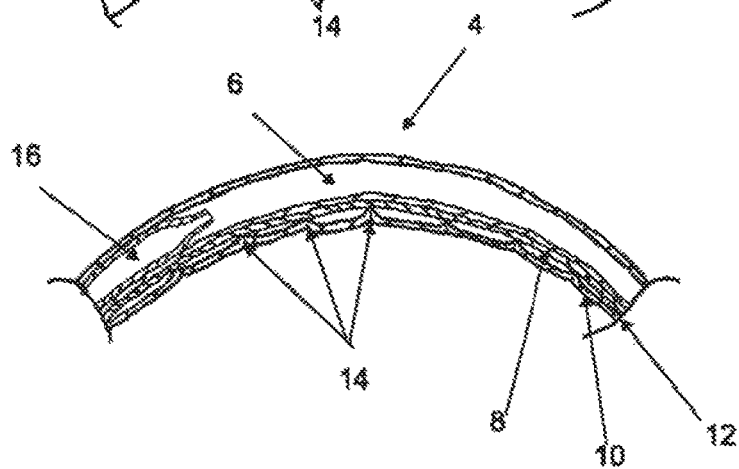
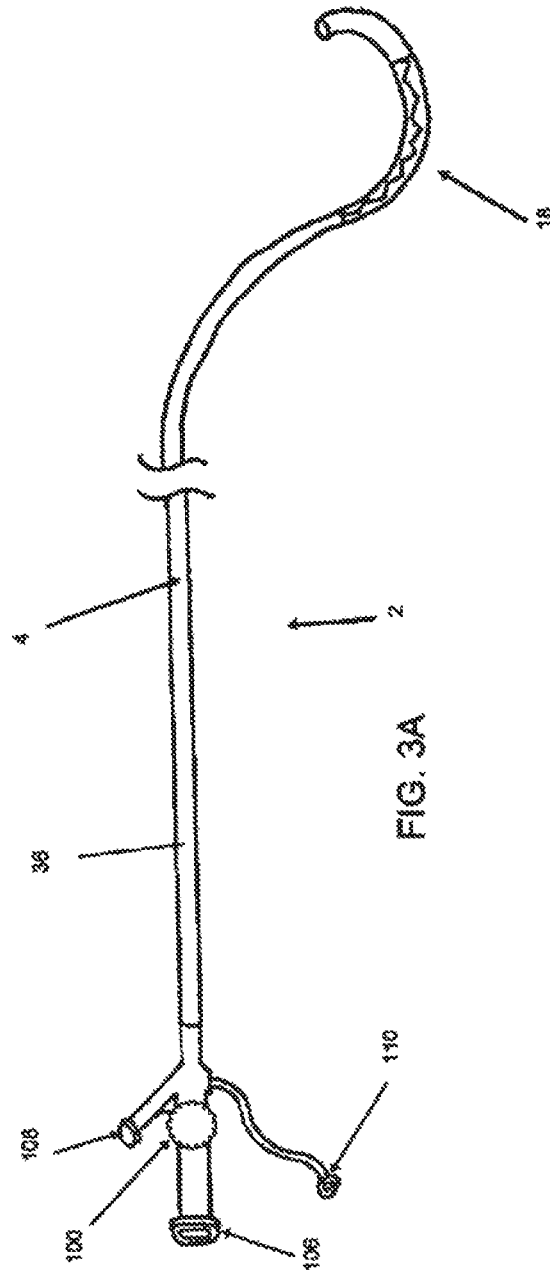
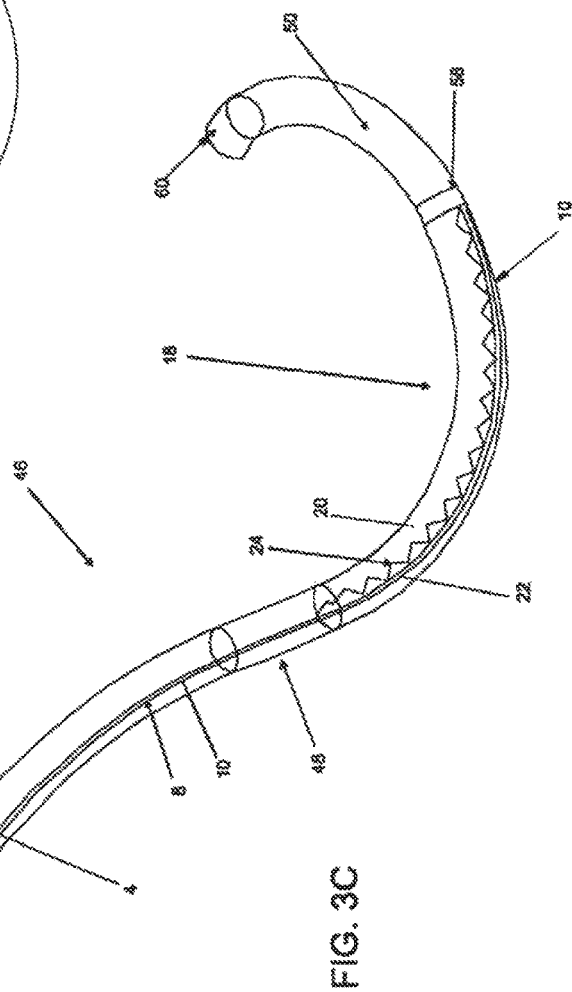
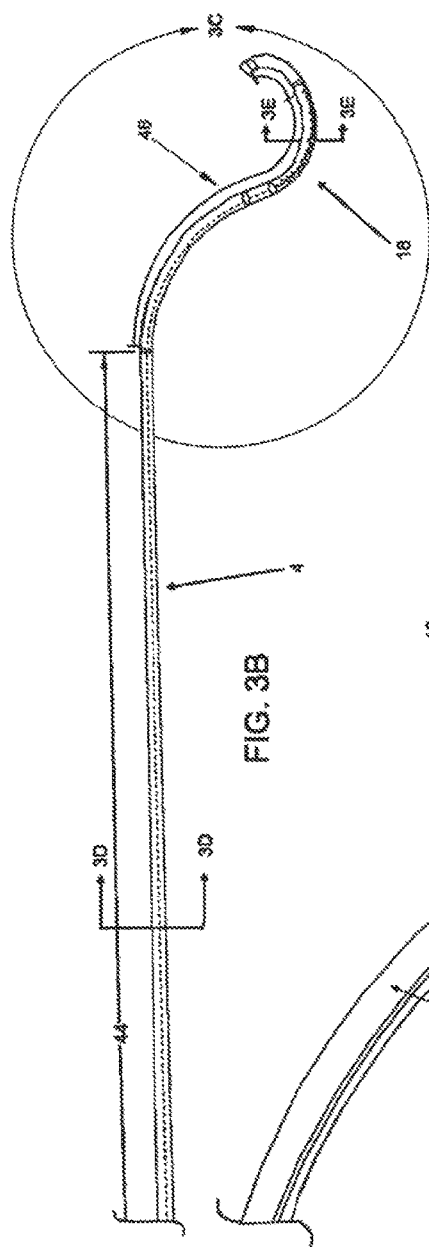


FIG. 2B







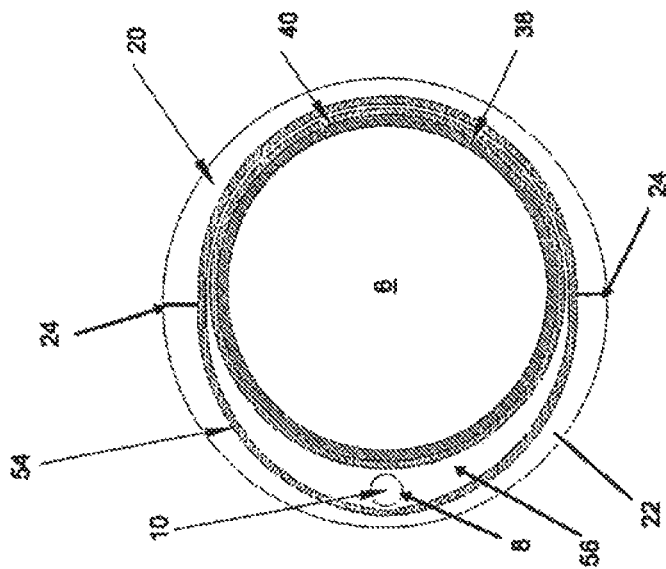


FIG. 3E

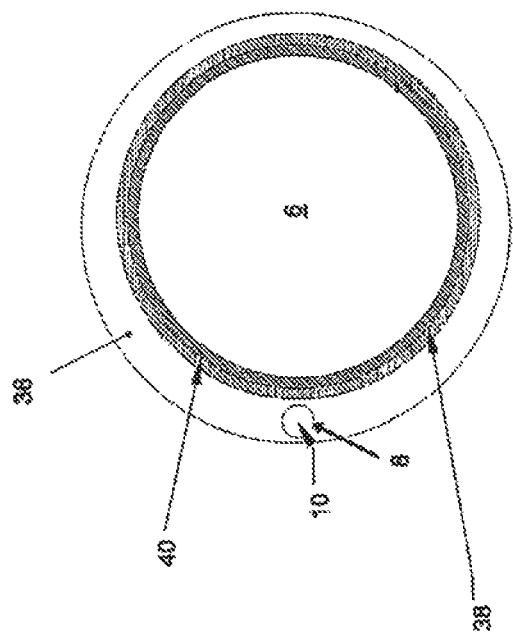


FIG. 3D

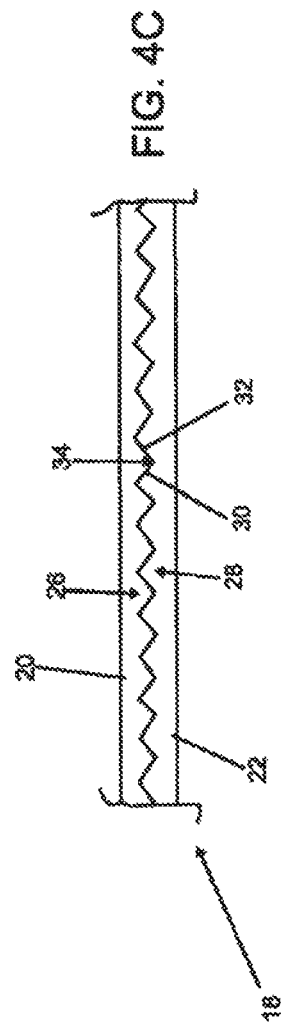
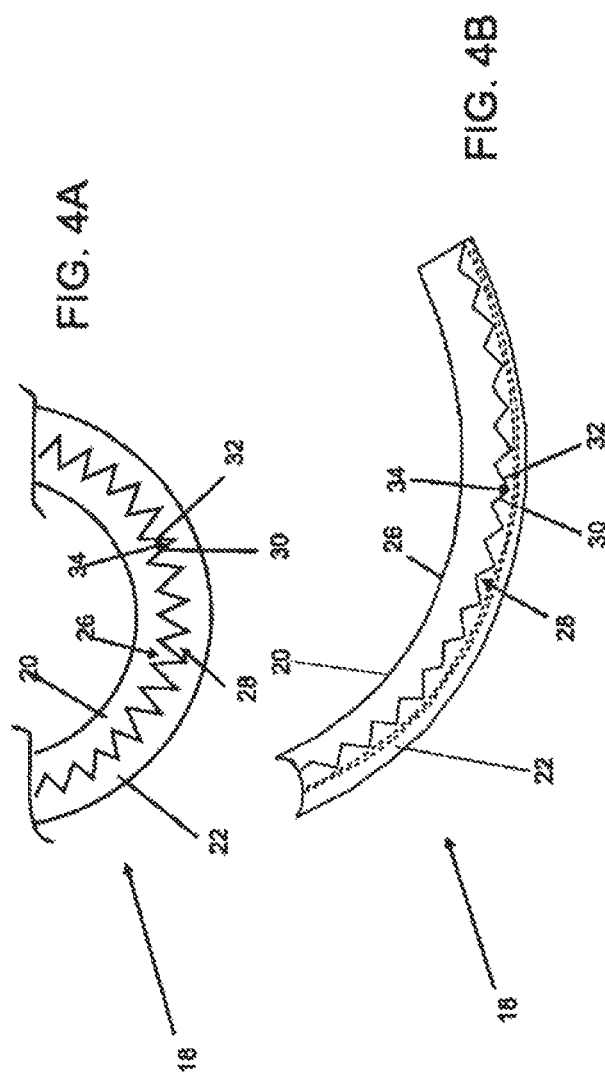


FIG. 5

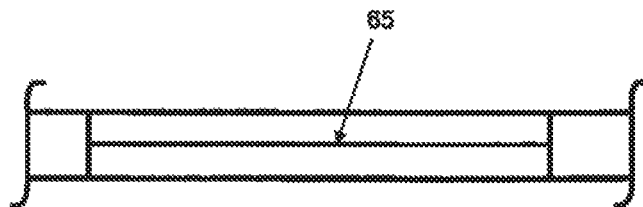


FIG. 6A

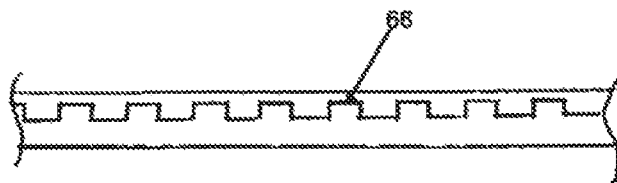


FIG. 6B

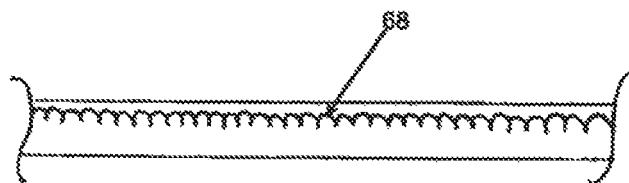


FIG. 6C

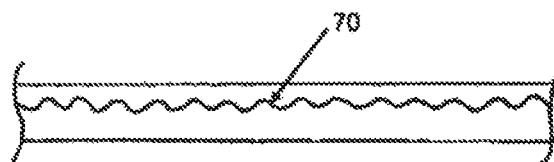
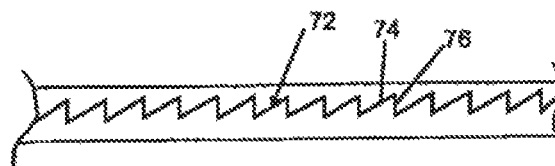


FIG. 6D



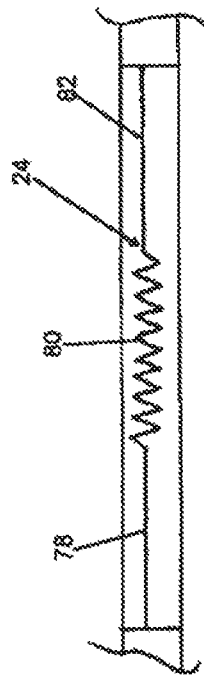


FIG. 7A

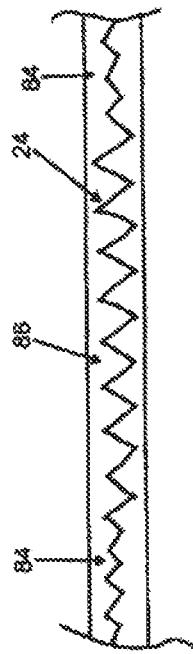


FIG. 7B

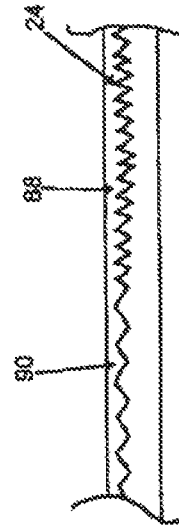


FIG. 7C

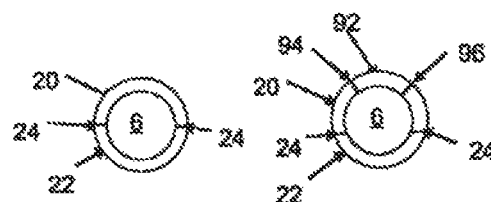
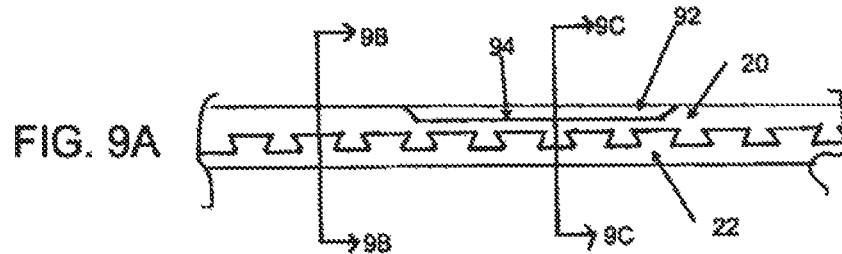
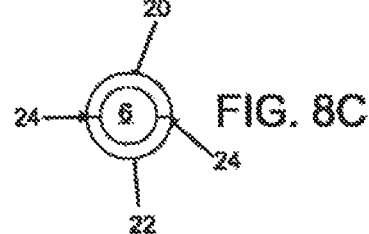
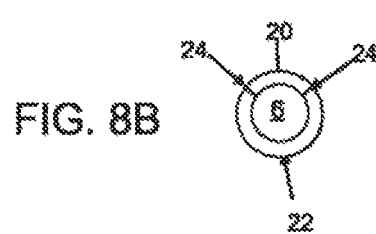
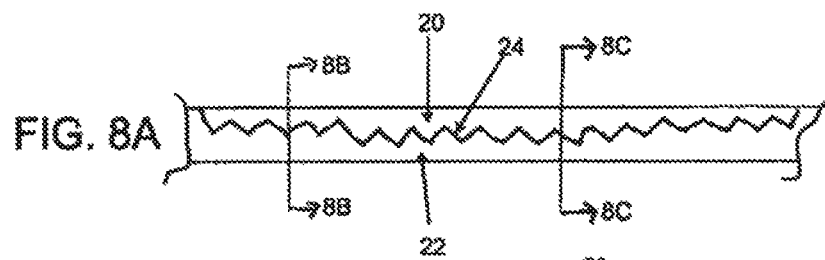


FIG. 9B

FIG. 9C

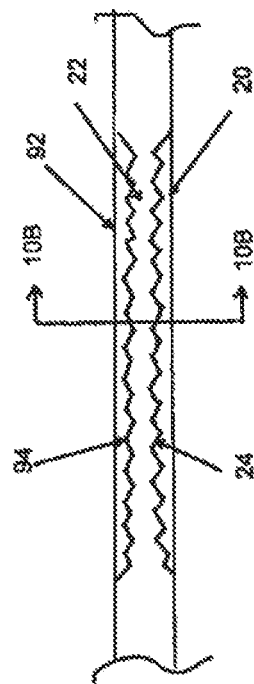


FIG. 10A

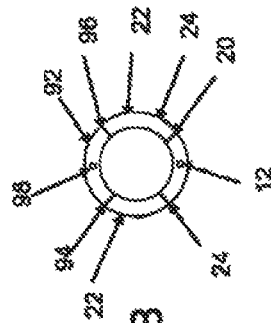
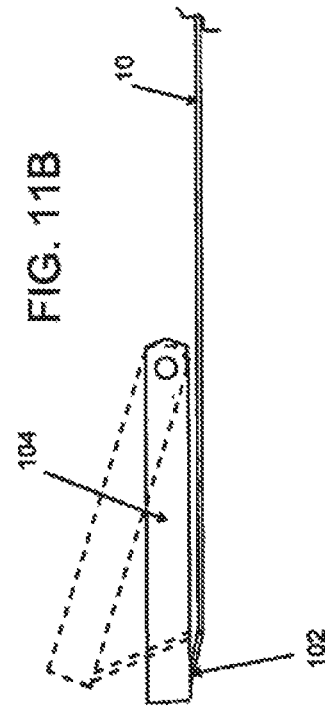
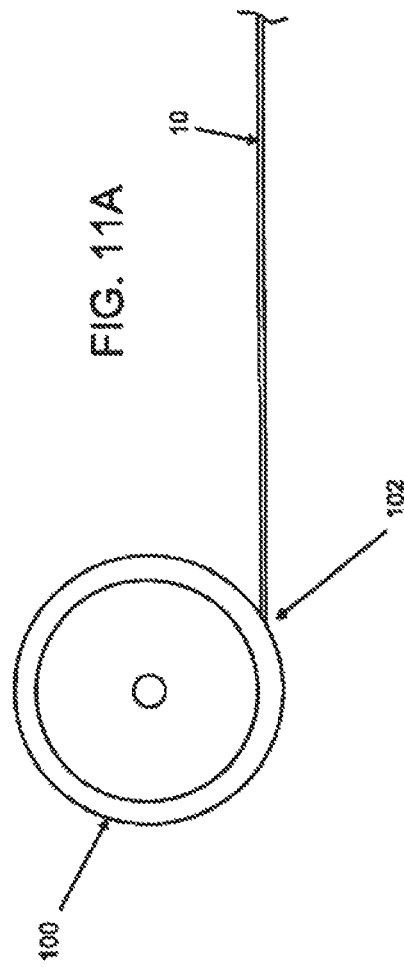
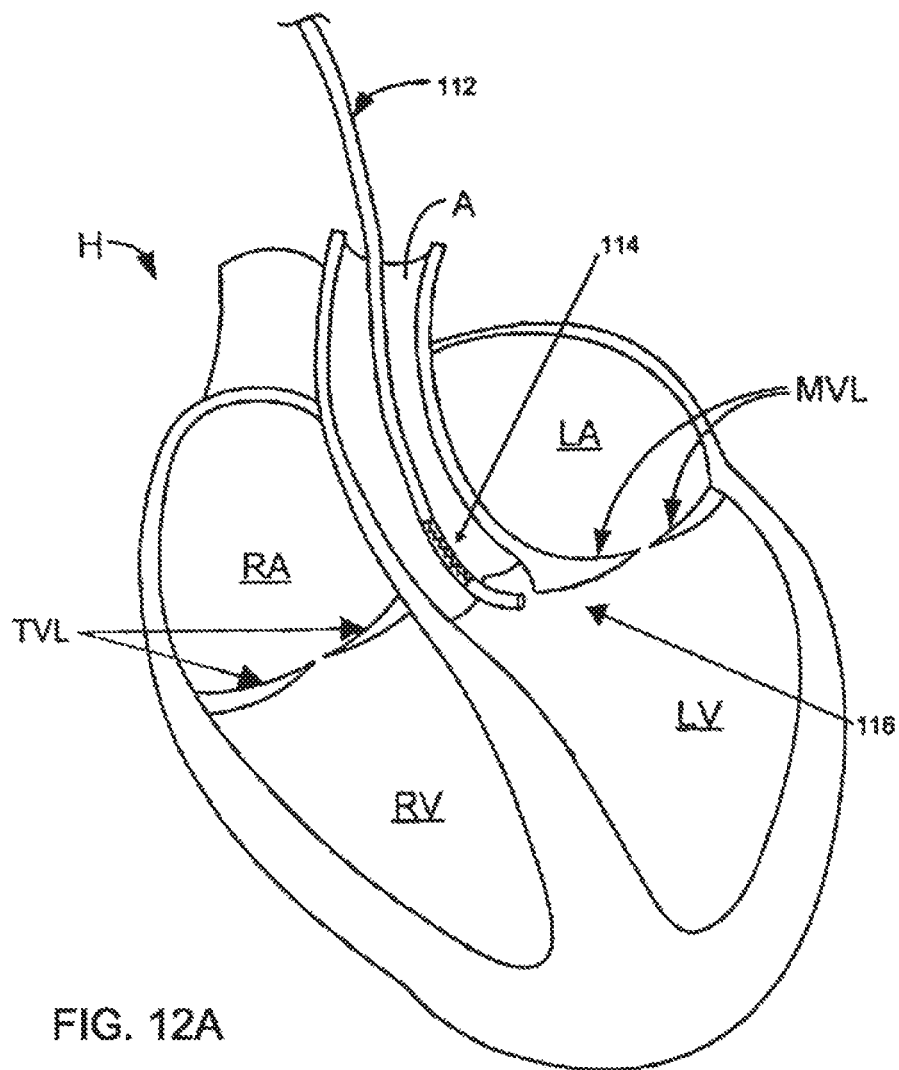


FIG. 10B





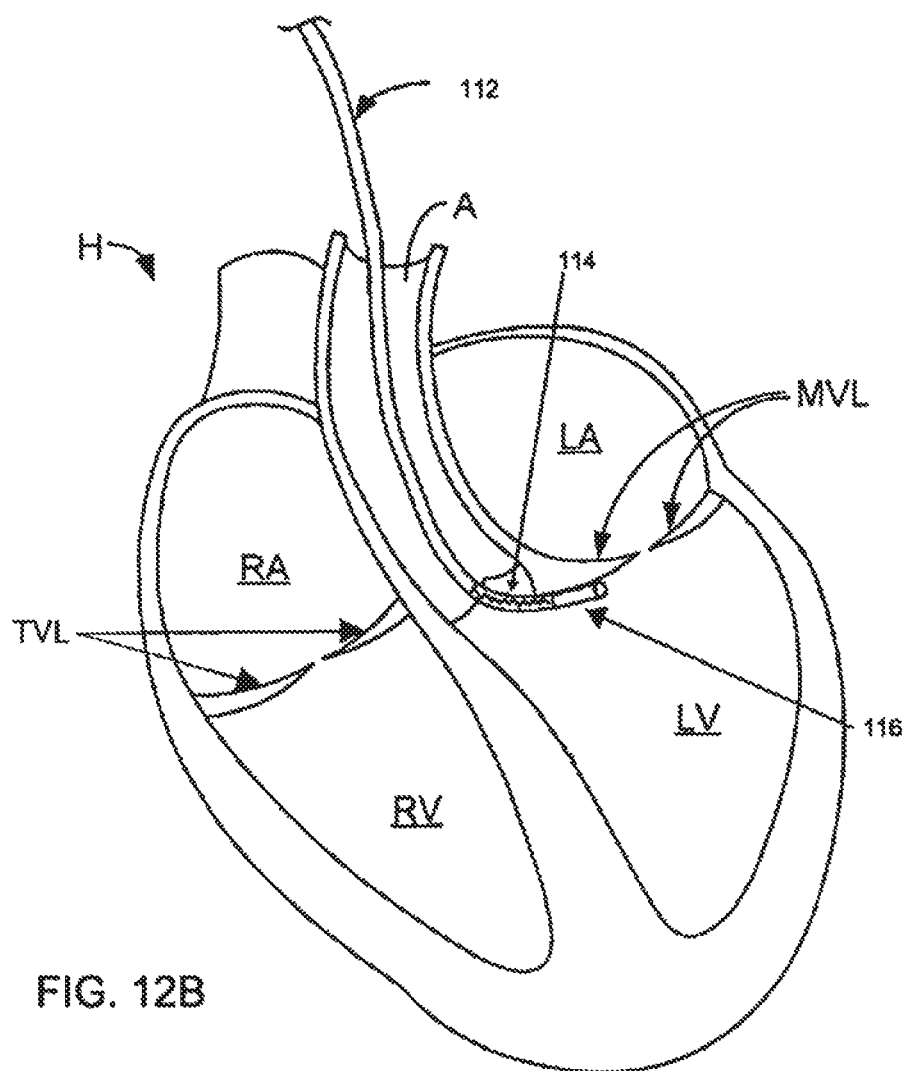


FIG. 13A

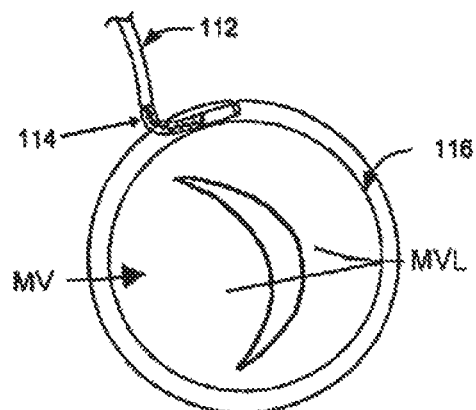


FIG. 13B

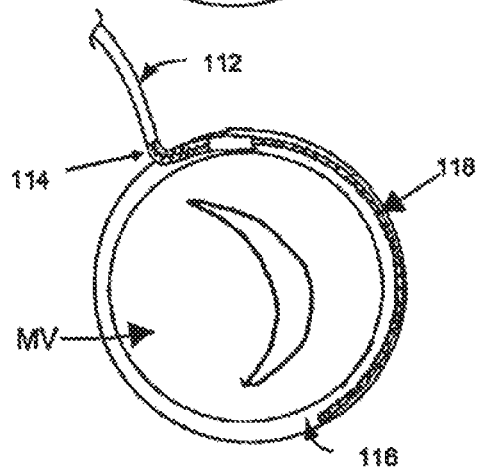


FIG. 13C

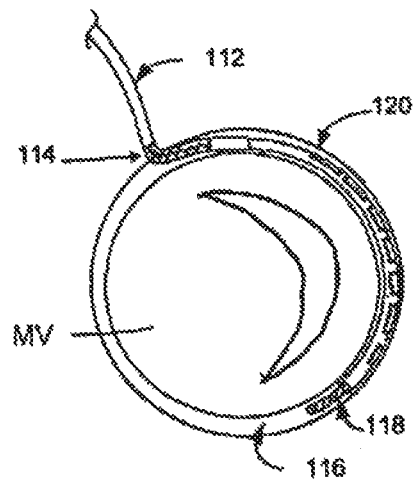


FIG. 13D

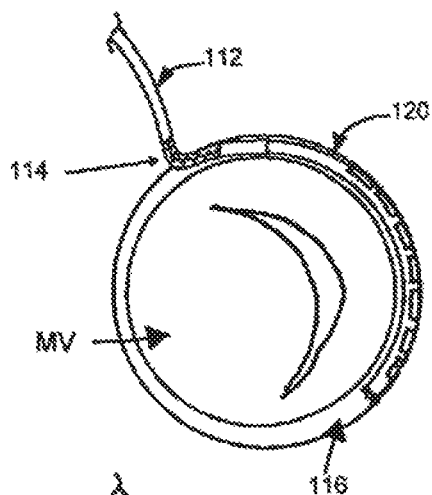
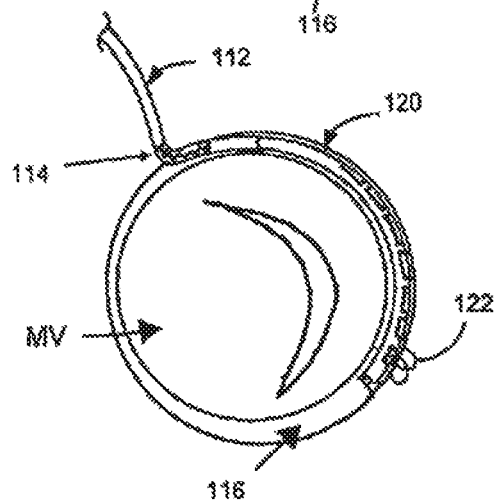
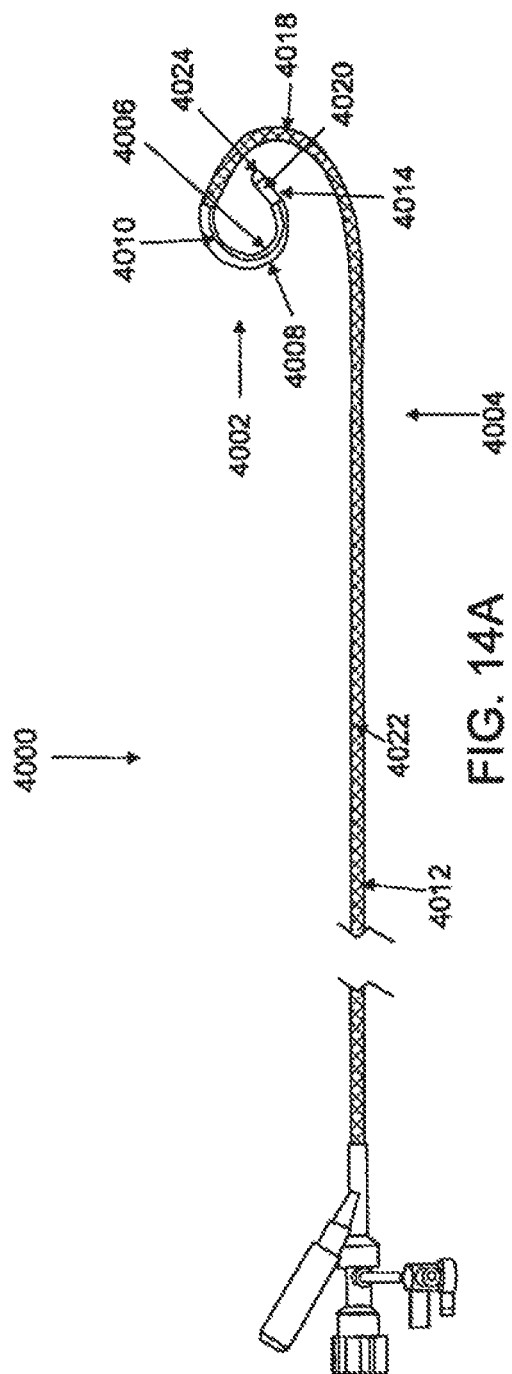
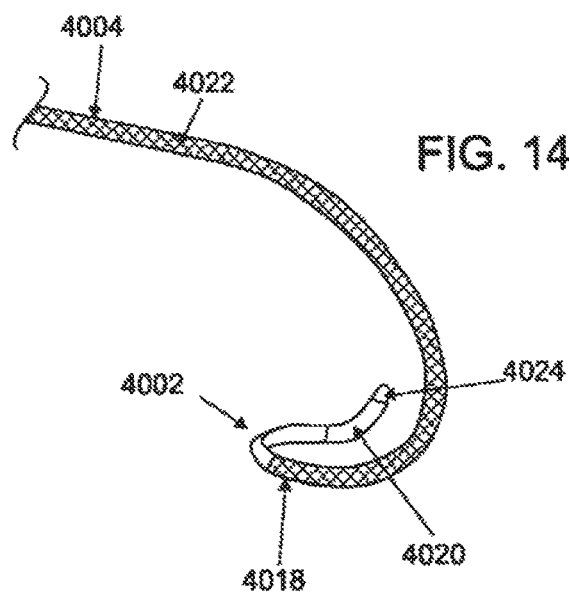
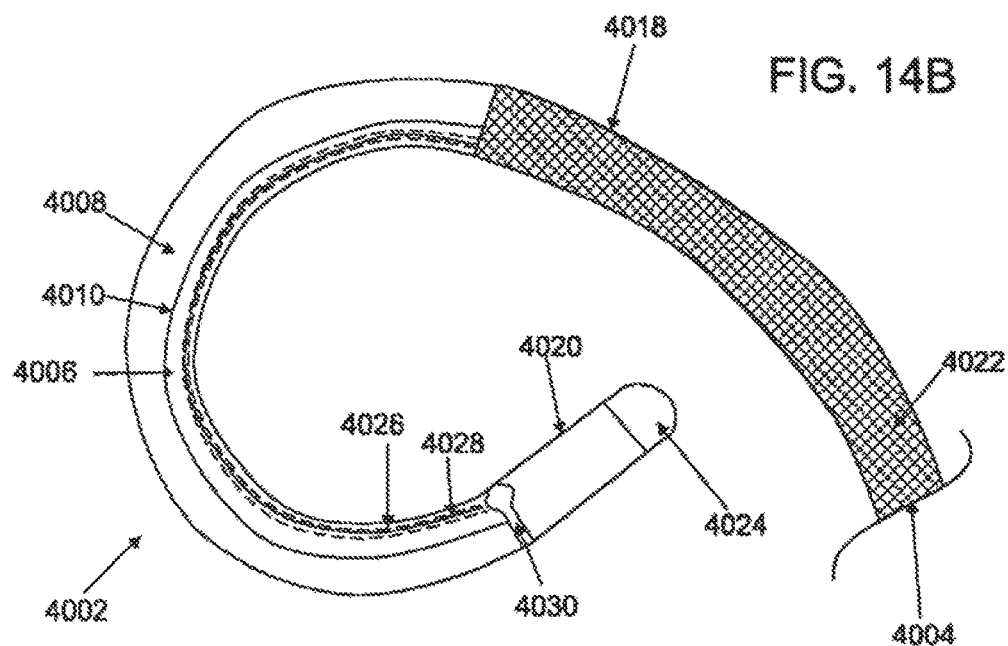
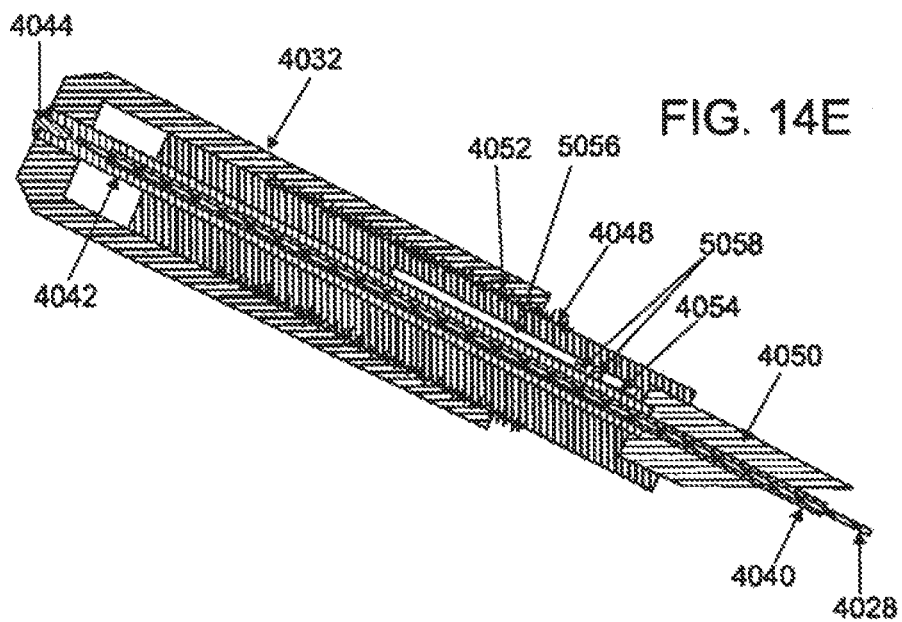
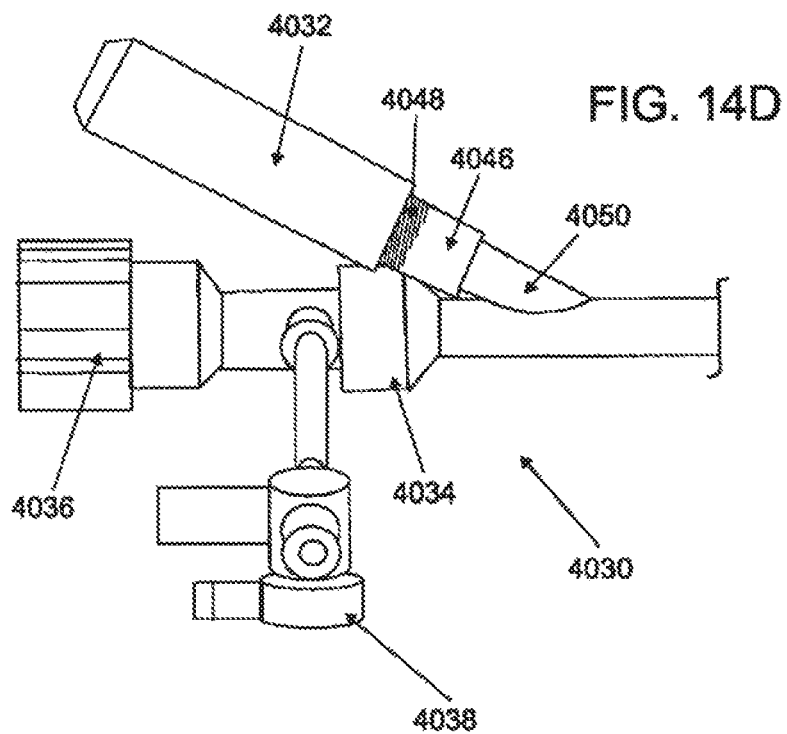


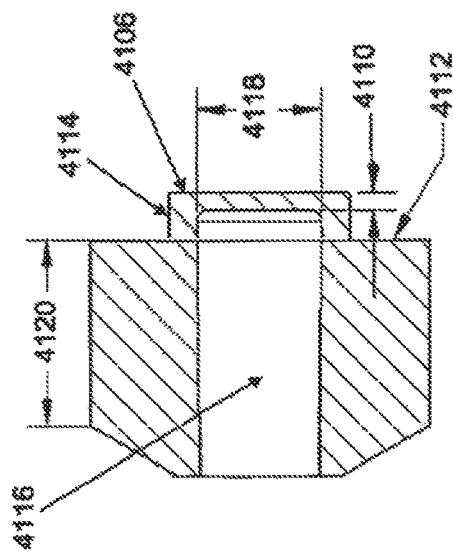
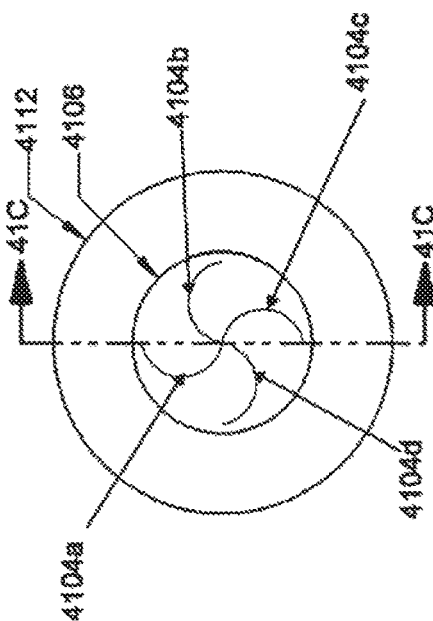
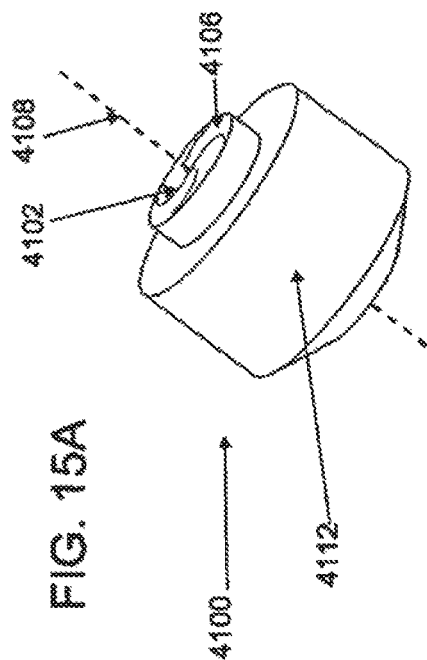
FIG. 13E

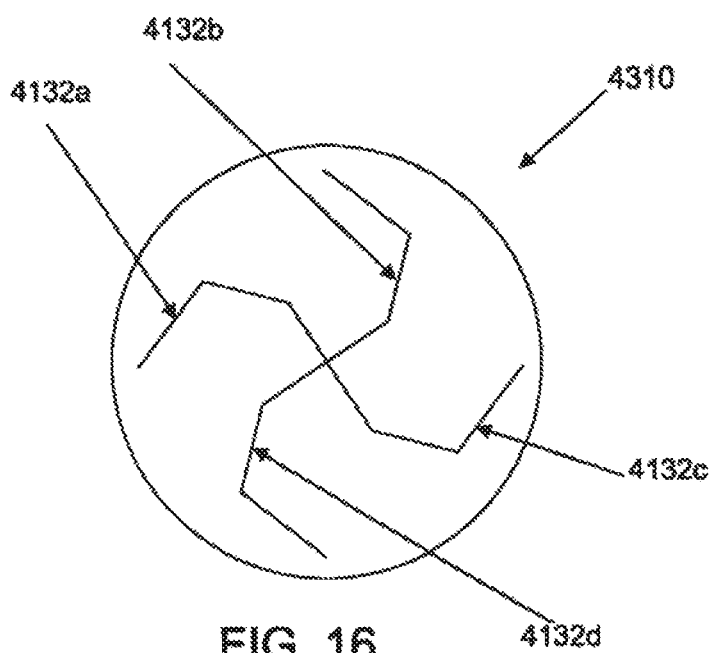












DEFLECTABLE GUIDE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. application Ser. No. 13/315,154, filed on Dec. 8, 2011, which is a divisional of U.S. application Ser. No. 12/437,495, filed on May 7, 2009, now issued as U.S. Pat. No. 8,096,985, which claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application Ser. No. 61/051,292, filed on May 7, 2008, and to U.S. Provisional Application Ser. No. 61/160,670 filed on Mar. 16, 2009, which are hereby incorporated by reference in their entirety.

BACKGROUND

Guide catheters are used in a variety of therapeutic and diagnostic medical procedures to facilitate insertion of instruments and implantable components. Guide catheters often comprise a rigid material or support structure to provide the torqueability and pushability characteristics that facilitate passage of the guide catheter to a particular site. With the stiffer material or support structure, the responsiveness of the distal portion of the guide catheter to manipulation of the proximal portion of the guide catheter typically improves. A flexible material, however, permits the guide catheter to navigate around tight bends and other hard-to-reach places. Although some guide catheters may be genetically configured for use with a variety of procedures, some guide catheters have a particular length, stiffness and distal tip shape adapted for access to a specific tissue or organ.

BRIEF SUMMARY

Described herein are devices and methods for guide catheters having one or more deformation zones. In one embodiment, a deformation zone comprises a tubular segment of the guide catheter with a longitudinal interface between two non-concentric sections of material having different durometers. The longitudinal interface may be linear or non-linear. A non-linear interface between the two sections of material, such as a zig-zag or sinusoidal interface, may permit controlled deformation of the lower durometer material between portions of higher durometer material. This deformation may include stretching and/or compression. In some embodiments, the deformation zone reduces the buckling of higher durometer material that may interfere with insertion or withdrawal of catheters or instruments from the lumen of the guide catheter.

In some embodiments, the guide catheter may further comprise a pull wire or ribbon which is secured to the guide catheter distal to the deformation zone and is slidable along a pull wire lumen through a proximal actuator. The pull wire may be used to control deflection of the guide catheter at the deformation zone. The actuator may be, for example, a rotatable knob, a pivoting lever or a slider. The actuator may comprise a bias element, such as a spring or other elastic element, that may be used to bias the pull wire toward a particular position. The actuator may also comprise a locking mechanism that may be used to maintain the pull wire in one or more positions.

In some embodiments, a catheter is provided, comprising a deformation zone comprising a proximal end, a distal end, a longitudinal length and a longitudinal axis therebetween, a lower durometer segment, a higher durometer segment,

and a first longitudinal interface between the lower durometer segment and the higher durometer segment, wherein the first interface has a length greater than the longitudinal length of the deformation zone. The lower durometer segment and/or the higher durometer segment may comprise a polymeric material. The first interface may have a non-linear configuration, including but not limited to a zig-zag configuration, or intercalating portions of the lower durometer segment and the higher durometer segment. In some embodiments, the deformation zone may further comprise a second interface between the lower durometer segment and the higher durometer segment, wherein the second interface is separate from the first interface. In one embodiment, the second interface may have a length greater than the longitudinal length of the deformation zone. In another embodiment, the deformation zone may have a first configuration and a second configuration, wherein the second configuration has an increased bend compared to the first configuration. The second configuration may be a curved configuration having a lesser curvature and a greater curvature, and wherein the lower durometer segment is located along the lesser curvature. In some further embodiments, the catheter may further comprise a means for controlling bending of the deformation zone. In some instances, the higher durometer segment has an angular width of at least about 45 degrees on an axial cross-section of the deformation zone. In other embodiments, the lower durometer segment has an angular width of at least about 90 degrees or at least about 180 degrees on the axial cross-section of the deformation zone.

In another embodiment, a catheter is provided, comprising a deformation zone comprising a proximal end, a distal end, a longitudinal length therebetween, a first polymeric layer comprising a proximal edge, a distal edge, a first lateral edge and a second lateral edge, and a second polymeric layer comprising a proximal edge, a distal edge, a first lateral edge and a second lateral edge, wherein the first polymeric material has a lower durometer than the second polymeric material, and wherein the first lateral edge of the first polymeric layer is joined to at least a portion of the second lateral edge of the second polymeric layer, and wherein the second lateral-edge of the first polymeric layer is joined to at least a portion of the first lateral edge of the second polymeric layer.

In another embodiment, a method for treating a patient is provided, comprising providing a catheter having a lower durometer region comprising at least one compressible portion and a greater durometer region comprising at least two constricting portions in an alternating configuration with the last least one compressible portion, bending the catheter such that the at least two constricting portions of the higher durometer region compresses the at least one compressible portion of the lower durometer region, and passing a tubular body down a passageway of the catheter.

In still another embodiment, a system for treating a patient is provided, comprising a guide catheter comprising a longitudinal axis, a guide lumen, and at least one deformation zone, the at least one deformation zone comprising two segments of polymeric material of different durometers and a longitudinal interface therebetween with respect to the longitudinal axis of the guide catheter, a tunnel catheter comprising a tubular body with a tunnel lumen, wherein the tubular body is configured for insertion into the guide lumen of the guide catheter, and a delivery catheter comprising an anchor retaining cavity and an anchor delivery mechanism, wherein the delivery catheter is configured for insertion into the tunnel lumen of the tunnel catheter. The tubular body of the tunnel catheter may further comprise a plurality of

delivery apertures in communication with the tunnel lumen. In some embodiments, the longitudinal configuration between the two segments of polymeric material comprises a reciprocating longitudinal configuration.

In one embodiment, a method for accessing a cardiac region of a patient is provided, comprising providing a steerable guide catheter comprising two polymeric materials forming a longitudinal interface therebetween, where the two polymeric materials comprise a first polymeric material having a first durometer and a second polymeric material having second durometer greater than the first durometer, passing the steerable guide catheter through a cardiac valve orifice, compressing the first polymeric material with the second polymeric material about the longitudinal interface, and steering the steerable guide catheter into a subvalvular region adjacent the cardiac valve orifice.

BRIEF DESCRIPTION OF THE DRAWINGS

The structure and method of using the invention will be better understood with the following detailed description, along with the accompanying illustrations, in which:

FIG. 1 is a cross-sectional view of a catheter body with a pull wire;

FIGS. 2A and 2B are schematic side elevation and cross sectional views of the catheter body of FIG. 1 in a bent configuration, respectively;

FIG. 3A illustrates one embodiment of a deflectable guide catheter; FIG. 3B is a detailed view of the catheter body of the deflectable guide catheter in FIG. 3A; FIG. 3C is a detailed view of the distal end of the deflectable guide catheter in FIGS. 3A and 3B; FIGS. 3D and 3E are various cross sectional views of the catheter body of FIG. 3B;

FIGS. 4A to 4C are schematic representations of a deformation zone in various configurations;

FIG. 5 represents one embodiment of the interface between two sections of catheter body material;

FIGS. 6A to 6D represent other embodiments of the interface between two sections of catheter body material;

FIGS. 7A to 7C represent various embodiments of the interface between two sections of catheter body material;

FIG. 8A illustrates one embodiment of a deformable zone of a deflectable guide catheter; FIGS. 8B and 8C represent various cross sections of the deformable zone depicted in FIG. 8A;

FIG. 9A illustrates another embodiment of a deformable zone of a deflectable guide catheter; FIGS. 9B and 9C represent various cross sections of the deformable zone depicted in FIG. 9A;

FIG. 10A illustrates another embodiment of a deformable zone of a deflectable guide catheter; FIG. 10B represents a cross section of the deformable zone depicted in FIG. 10A;

FIG. 11A is a schematic representation of one embodiment of a steering mechanism; FIG. 11B is a schematic representation of another embodiment of a steering mechanism;

FIGS. 12A and 12B depict one embodiment of a deflectable guide catheter used to reach the subvalvular groove region of a mitral valve; and

FIGS. 13A to 13E are schematic representations of a deflectable guide catheter used to implant a cinchable implant along the subvalvular region of a mitral valve.

FIG. 14A is a superior elevational view of a variation of a steerable guide catheter; FIG. 14B is a detailed superior elevational view of the distal end of the guide catheter; FIG. 14C is a side elevational view of the distal end of the guide catheter; FIG. 14D is a detailed superior elevational view of

the proximal end of the guide catheter; and FIG. 14E is a longitudinal cross sectional view of the steering mechanism of the guide catheter.

FIG. 15A is a perspective view of a variation of a hemostatic seal; FIG. 15B is a posterior elevational view of the seal; and FIG. 15C is a cross-sectional view of the seal.

FIG. 16 is a posterior elevational view of another variation of a hemostatic seal.

DETAILED DESCRIPTION OF THE INVENTION

The case of inserting a catheter to a body location may be influenced by a number of catheter characteristics. While a catheter made from stiffer materials may improve its user responsiveness relating torqueability and pushability over longer insertion distances, stiffer catheter materials may affect the catheter's maneuverability through tight anatomical bends. In some cases, catheter maneuverability may be improved by using a steering mechanism to position the catheter tip in the desired orientation or direction. FIG. 1 illustrates one example of a steerable catheter segment, comprising a tubular catheter body 4 with one or more conduits 6 and a pull lumen 8 containing a pull member 10. Typically, pull member 10 is attached distally to catheter body 4 such that, when pulled proximally, pull member 10 will cause catheter body 4 to bend, as shown in FIG. 2A. While a steering mechanism 12 may improve the bending range of stiffer catheter materials, such materials may cause creases 14 or other discontinuities in catheter body 4 when bent, as illustrated in FIG. 2A. Further, such creases 14 may impair the ability to pass instruments 16 or components down conduit 6, as shown in the cross-sectional view of FIG. 2B.

In one embodiment, shown in FIG. 3A, a steerable catheter 2 with one or more deformation zones 18 is provided. Referring to FIG. 3C, deformation zone 18 may comprise a segment of catheter body 4 comprising a first layer segment 20 and a second layer segment 22 arranged with a longitudinal interface 24 therebetween. First layer segment 20 and second layer segment 22 comprise different physical characteristics such that first layer segment 20 is able to compress or stretch when flexed. In some embodiments, first layer segment 20 comprises a material having a lower durometer than second layer segment 22. In embodiments where deformation zone 18 is formed by two layer segments, two longitudinal interfaces are formed where the two lateral borders of each layer segment form a longitudinal interface with the complementary lateral border of the other layer segment. In other embodiments, first layer segment 20 may comprise a structural geometry, such as surface cuts or grooves, that may help control or distribute flexion forces to reduce impingement of any conduits.

In some embodiments, longitudinal interface 24 generally has a linear or simple curve configuration similar to the longitudinal axis of catheter body 4. In the embodiment depicted in FIG. 3C, however, longitudinal interface 24 is oriented with a similar axis as the longitudinal axis of catheter body 4 but with a zig-zag configuration. Referring to FIG. 4A, the zig-zag configuration of longitudinal interface 24 comprises alternating protruding sections of first layer segment 20 and second layer segment 22. These alternating protruding sections, shown in this particular embodiment as triangular sections 26 and 28, have side lengths 30 and 32 which meet to form an angle 34 between two adjacent sides 30. In FIG. 4C, when deformation zone 18 is straightened from its configuration in FIG. 4B, trian-

5

gular sections 26 of first layer segment 20 are stretched or relieved of compression as angle 34 is increased by the angular separation of triangular sections 28 of second layer segment 22. In contrast, as depicted in FIG. 4A, when deformation zone 18 is acutely bent relative to FIG. 4A, triangular sections 26 of first layer segment 20 are compressed as angle 34 is decreased by the angular reduction of triangular sections 28 of second layer segment 22. In some embodiments of the invention, the zig-zag pattern may reduce the incidence or degree of pinching or creasing of any conduits in catheter body 4 by controlling compression of the lower durometer material in first layer segment 20 with the protruding sections 28 of the higher durometer material in second layer segment 22. Further, in some embodiments, the zig-zag pattern may provide a more even distribution of the forces along the full length of deformation zone 20, compared to simple linear or simple curved interfaces. In some embodiments, second layer segment 22 may be contiguous with tubular body 36.

In one embodiment, deformation zone 18 is configured to bend from about 180 degrees to about 30 degrees, about 180 degrees to about 45 degrees in some embodiments, and about 180 degrees to about 90 degrees in other embodiments. In some embodiments, deformation zone 18 is able to bend in two or more directions and/or two or more planes from its straight or base configurations. The range of bending in two or more directions or planes need not be symmetrical with respect to the straight or base configurations. The base configuration need not be linear. Various embodiments of non-linear base configurations are discussed later.

In some embodiments, catheter body 4 may have a total length of about 20 cm to about 200 cm or more, about 60 cm to about 160 cm in other embodiments, and about 100 cm to about 120 cm in still other embodiments. In one embodiment, catheter body 4 may have an outer diameter of about 5 F to about 34 F, in other embodiments about 8 F to about 20 F, and about 12 F to about 16 F in some embodiments. In some embodiments of the invention, conduit 6 is sized to accept catheters or instruments with a size of about 3 F to about 30 F, in a few embodiments about 6 F to about 16 F, and about 8 F to about 12 F in other embodiments.

Catheter body 4 can be formed from any of a variety of materials. Examples of suitable materials include but are not limited to polymers, such as polyether-block co-polyamide polymers, copolyester elastomers, thermoset polymers, polyolefins (e.g., polypropylene or polyethylene, including high-density polyethylene and low-density polyethylene), polytetrafluoroethylene, ethylene vinyl acetate, polyamides, polyimides, polyurethanes, polyvinyl chloride (PVC, fluoropolymers (e.g., fluorinated ethylene propylene, perfluoroalkoxy (PFA) polymer, polyvinylidene fluoride, etc.), polyetheretherketones (PEEKs), Polyetherketoneketones (PEKKs) and silicones. Examples of polyamides that may be included in tunnel catheter (410) include Nylon 6 (e.g., Zytel® HTN high performance polyamides from DuPont™), Nylon 11 (e.g., Rilsan® B polyamides from Arkema Inc.), and Nylon 12 (e.g., Grilamid® polyamides from EMS-Grivory, Rilsan® A polyamides from Arkema Inc., and Vestamid® polyamides from Degussa Corp.). In one embodiment, catheter body 4 comprises PEBAX®, a polyether block amide (PEBA) available from ATOM-CHEM POLYMERS of Birdsboro, Pa. First layer segment 20 and second layer segment 22 may comprise different materials or the same general type of material but with different durometers. In some embodiments, the durometer of the material may range from about 5 D to about 72 D, sometimes about 35 D to about 72 D, other times about 35

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D to about 55 D, or about 55 D to about 72 D. Catheter body 4 may comprise one or more layers, and sometimes two or more layers. Although FIGS. 3A to 3C depict first layer segment 20 and second layer segment 22 as forming the outermost layer of deformation zone 18, in other embodiments of the invention, these layer segments 20 and 22 may be covered by one or more other layers or reinforcing structures. Catheter body 4 need not comprise the same number of polymeric layer along its entire length.

Catheter body 4 and/or conduits 6 may be reinforced (e.g., with tubular or arcuate braiding, circular loops, helical structures, or longitudinal supports). The reinforcing structure or structures may comprise a metallic material or a non-metallic material. Metallic materials that may be used include but are not limited to stainless steel such as 316L, nitinol and cobalt-chromium.

Referring back to the specific embodiment depicted in FIGS. 3A and 3B, catheter body 4 may comprise a proximal section 44 and a distal section 46. Referring to FIG. 3D, in this specific embodiment, proximal section 44 comprises a tubular body 36 and a single conduit 6 optionally lined with a coating 38. Typically, proximal section 44 has a linear configuration, but in other embodiments, proximal section 44 may have a non-linear configuration, including angled and curved configurations or combinations thereof. In some embodiments, tubular body 36 optionally comprises one or more reinforcement structures 40. In some embodiments, tubular body 36 may comprise PEBAX 72D, coating 38 may comprise PTFE and reinforcement structure 40 may comprise a tubular stainless steel wire braid surrounding conduit 6. Proximal section 44 further comprises a pull lumen 8 and pull member 10 within the wall of proximal section 44. Pull lumen 8 and/or pull member 10 may also be coated with a lubricious coating such as PTFE. In further embodiments, pull lumen 8 may be reinforced with a material such as polyimide. As shown in FIG. 4D, in some embodiments of the invention, the wall thickness of catheter body 4 or proximal section 36 may vary along their longitudinal lengths or circumferences.

In some embodiments, distal section 46 may comprise a particular shape with optional multiple sections. For example, as shown in FIG. 3C, distal section 46 may comprise a pre-deformation section 48, a second section comprising deformation zone 18, a post-deformation section 50 and a distal tip 52. In this particular embodiment, pre-deformation section 48 comprises a curved configuration but otherwise may have similar components as proximal section 44, with a tubular body 36, conduit 6, and pull member 10 within pull lumen 8. In other embodiments of the invention, the components and features of pre-deformation section 48 may be different from proximal section 44. In this particular embodiment, distal to pre-deformation section 48 is deformation zone 18 configured with a curved configuration with a curvature opposite of pre-deformation section 48. In other embodiments of the invention, deformation zone 18 may have a linear or angled configuration, with an angular orientation from about 0 degrees to about 359 degrees with respect to pre-deformation section 48. In some embodiments, deformation zone 18 may have an angular orientation of about 0 degrees, about 15°, about 30°, about 45°, about 60°, about 75°, about 90°, about 105°, about 120°, about 135°, about 150°, about 165°, about 180°, about 195°, about 210°, about 225°, about 240°, about 255°, about 270°, about 285°, about 300°, about 315°, about 330°, or about 345°. The bending plane of deformation zone 18, however, need not be the same plane as its curved configuration and may have an angular orientation from about 0

degrees to about 359 degrees to the plane of its curved configuration. In some embodiments, the bending plane of deformation zone has an angular orientation of about In some embodiments, deformation zone 18 may have an angular orientation of about 0 degrees, about 15°, about 30°, about 45°, about 60°, about 75°, about 90°, about 105°, about 120°, about 135°, about 150°, about 165°, about 180°, about 195°, about 210°, about 225°, about 240°, about 255°, about 270°, about 285°, about 300°, about 315°, about 330°, or about 345° with respect to the plane of its curved configuration.

In some embodiments, deformation zone 18 may have a longitudinal length of about 0.75 inches to about 10 inches, some embodiments about 1 inch to about 4 inches or more, and in other embodiments about 1.5 inches to about 2 inches in length. In some embodiments of the invention, deformation zone 18 may have similar inner and outer diameters as described for catheter body 4, but in other embodiments, deformation zone 18, the inner diameter of conduit 6 may be smaller or larger and the outer diameter of tubular body 36 may be smaller or larger.

Referring to FIG. 3E, in this specific embodiment, deformation zone 18 comprises an outer layer 42 formed by first layer segment 20 and second layer segment 22. Conduit 6, pull lumen 8, pull member 10 and reinforcement structure 40 are arranged in deformation zone 18 similar to proximal section 44, except that a second reinforcement structure 34 is provided. In this embodiment, second reinforcement structure 54 comprises a second tabular stainless steel braid surrounding conduit 6 and pull lumen 8. In some embodiments, second reinforcement structure 54 may originate proximally in pre-deformation section 48 of distal section 46. The portion 56 of tubular body 36 between reinforcement structures 40 and 54 may comprise a similar material as segments 20 or 22, or a different material.

Although several embodiments depicted and described herein have a single conduit 6, in other embodiments, two or more conduits may be provided. Embodiments of the invention with multiple conduits need not have conduits with the same diameter, shape or cross-sectional area. Furthermore, any one conduit need not have the same diameter, shape or cross-sectional area along its entire length. Thus, some conduits may comprise a circular shape, but in other embodiments the conduits may be oval, square, rectangular or any other shape. As mentioned previously, in some embodiments of the invention, conduit 6 may comprise a lubricious coating, including but not limited to PTFE.

In some embodiments, catheter body 4 may also comprise one or more radio-opaque structures or materials to facilitate identification and localization of guide catheter 2 with radiographic imaging. The imaging may include but is not limited to fluoroscopy, CT imaging, MRI imaging, and intravascular ultrasound or echocardiography. The radio-opaque structures may be found along the entire length or a portion of the length of catheter body 4. In some embodiments, at least one radio-opaque structure is located at post-deformation section 50 or distal tip 60.

As mentioned previously, segments 20 and 22 may be joined at their lateral edges to form two longitudinal interfaces 24. In this specific embodiment, segment 20 comprises PEBAX 35D while segment 22 comprises PEBAX 72D. Because segments 20 and 22 in this specific embodiment have generally semi-circular configurations, longitudinal interfaces 24 have generally 180 degree opposite locations with respect to conduit 6. In other embodiments, however, deformation zone 18, interfaces 24 may be angularly closer together, or may comprise three or more interfaces 24.

Referring back to FIG. 3C, in some embodiments, distal section 46 further comprises a post-deformation section 50 distal to deformation zone 18. Post-deformation section 50 may be straight, angled or curved, or a combination thereof. Post-deformation section 50 may have a longitudinal length of about 0.25 inches to about 5 inches or more, sometimes about 0.5 inches to about 2 inches, and occasionally about 0.75 inches to about 1.25 inches. Post-deformation section 50 may comprise one or more layers. In some embodiments, post-deformation section 50 comprises the same material as one of the segments from deformation zone 18, but in other embodiments, post-deformation section 50 may comprise a material having a higher, lower or intermediate durometer. For example, in one embodiment of the invention, segments 20 and 22 of deformation zone 18 comprise PEBAX 35D and 72D, respectively, while post-deformation section 50 comprises PEBAX 55D. Post-deformation section 50 may or may not include one or more reinforcement structures. In some embodiments, the reinforcement structure may be contiguous with reinforcement structures 40 and/or 54, and in some embodiments may include a reinforcement structure different from reinforcement structure 40 and/or 54.

In some embodiments, one or more conduits from the proximal portions of catheter body 4 may pass through post-deformation section 50 or terminate within it. In embodiments of the invention with a single deformation zone and/or steering mechanism, however, pull lumen 8 and/or pull member 10 may terminate within post-deformation section 50. To facilitate the exertion of force in distal section 46 of catheter body 4, pull member 10 may comprise a distal pull structure 58. Pull member 10 may be coupled to distal pull structure 58 or be contiguous with distal pull structure 58. In the embodiment illustrated in FIG. 3C, distal pull structure 58 may comprise a ring-like structure embedded in post-deformation section 50. In alternate embodiments, distal pull structure 58 may comprise a helical winding of pull member 10 or some other wire-based configuration. Pull member 10 may comprise any of a variety of materials and structures sufficient to transmit longitudinal forces along a length of catheter body 4. Pull member 10 and distal pull structure 58 may be metallic, non-metallic or a combination thereof, including but not limited to stainless steel, nitinol, nylon or other polymeric material. In some embodiments, pull member 10 may be coated, for example, to facilitate sliding in pull lumen 8. Such coatings may include PTFE.

In some embodiments, pull member 10 may comprise a structure and a material whereby pull member 10 can exert force on catheter body 4 only when pulled. In these embodiments, catheter body 4 may have a preconfigured shape such that when the force acting on pull member 10 is released, catheter body 4 is biased to return to its preconfigured shape. In other embodiments, pull member 10 has a sufficient stiffness such that pull member 10 may also be pushed to facilitate bending of catheter body 4 in a direction generally different or opposite from the bending that occurs when pull member 10 is pulled. In other embodiments of the invention, distal pull structure 58 may be located within deformation zone 18.

As depicted in FIG. 3C, catheter body 4 may optionally comprise a distal tip 60 with a different structure or configuration relative to post-deformation section 50. In embodiments, distal tip 60 is configured as an atraumatic tip and may comprise a material and/or structure different from tubular body 36, deformation zone 18 or post-deformation section 50. In some embodiments, distal tip 60 comprises a material with a durometer equal to or lower than a material

found in either deformation zone **18** or post-deformation section **50**. In one specific example, distal tip **60** comprises PEBAX 35D, while post-deformation section **50** comprises PEBAX 55D, segment **20** comprises PEBAX 35D, segment **22** comprises PEBAX 72D and tubular body **36** comprises PEBAX 72D. Distal tip **60** may have a longitudinal length of about 1 mm to about 20 mm or more, sometimes about 2 mm to about 10 mm, and occasionally about 5 mm. The inner and outer diameters of distal tip **60** may be the same or different from other portions of catheter body **4**.

In some embodiments, interface **24** may have a relatively linear configuration **65**, as depicted in FIG. 5, or a non-linear configuration other than a zig-zag pattern. For example, interface **24** may comprise a reciprocating pattern including but not limited to a square wave pattern **66**, a scalloped pattern **68**, and a sinusoidal pattern **70** as depicted in FIGS. 6A to 6C, respectively. As shown in FIG. 6D, the reciprocating pattern **72** need not have symmetric subsegments. In this embodiment for example, the leading edge **74** has a different length and angle as the trailing edge **76**.

As depicted in FIGS. 7A to 7C, interface **24** need not comprise the same repeating pattern along its entire length. For example, in the embodiment depicted in FIG. 7A, interface **24** comprises a linear portion **78** followed by a zig-zag portion **80** and another linear portion **82**. In another embodiment depicted in FIG. 7B, interface comprises the same pattern but with sections of low and high amplitude **84** and **86**, respectively. In still another embodiment shown in FIG. 7C, interface **24** comprises a pattern of similar amplitude but contains portions with relatively shorter and longer repeating lengths **88** and **90**, respectively. These features may be mixed and matched to achieve the desired structural features in deformation zone **18**.

As mentioned previously, the embodiment depicted in FIGS. 3A to 3E comprises a deformation zone **18** with two similarly sized semi-circular segments **20** and **22**, and two interfaces **24** about 180 degrees apart with respect to conduit **6**. In other embodiments, however, segments **20** and **22** may have different sizes and shapes. In FIG. 8A, for example, segment **20** has a reduced width at one or more ends, resulting in interfaces **24** forming a narrower angle in one section (FIG. 8B) as compared to another section (FIG. 8C). In other embodiments of the invention, as depicted in FIG. 9A, the deformation zone may comprise a third layer segment **92**, resulting in additional interfaces **94**, **96**.

In some embodiments, such as the embodiment depicted in FIGS. 3A to 3E, deformation zone **18** comprises a single steering mechanism **12**, but in other embodiments, multiple pull lumens with multiple pull members may be provided. In FIG. 10A, for example, the deformation zone comprises three layer segments **20**, **22** and **92** arranged to facilitate the bending of the deformation zone in opposite directions. As shown in FIG. 10B, two steering mechanisms **12** and **98** may be provided to facilitate bending in opposite directions. In other embodiments, the two or more steering mechanisms may be located about 15°, about 30°, about 45°, about 60°, about 75°, about 90°, about 105°, about 120°, about 135°, about 150°, about 165°, about 180°, about 195°, about 210°, about 225°, about 240°, about 255°, about 270°, about 285°, about 300°, about 315°, about 330°, or about 345° with respect to the plane of its curved configuration. In other embodiments of the invention, multiple steering mechanisms with different distal longitudinal terminations along the length of catheter body **4** may be provided, to facilitate along different lengths of bending. The longitudinal separation

may be about 1 cm to about 50 cm or more, sometimes about 5 cm to about 20 cm, and at other times about 5 cm to about 10 cm apart.

Any of a variety of control mechanisms may be used to manipulate one or more pull members **10**. In FIG. 3A, for example, a rotatable knob **100** may be provided on steering catheter **2**. Referring to FIG. 11A, the proximal end **102** of pull member **10** may be attached to a rotating knob **102**, or alternately to a pivoting lever **104**, as illustrated schematically in FIG. 11B. In other embodiments, pull member **10** may be manipulated by a pull ring or a slider. Steering mechanism **12** may further comprise a bias member (not shown), such as a spring or elastic member, to bias distal section **46** to a particular position. Steering mechanism may also comprise a releasable locking mechanism to maintain pull member **10** in a desired position.

In some embodiments, the knob **100** or other proximal control member is coupled to a single pull member. In other embodiments with multiple pull members, one or more control members may be provided, particularly in embodiments with multiple deformation zones, but the number of control members need not be equal to the number of pull members. In these embodiments, two or more pull members may be coupled to a single control member. For example, a knob or slider may be engaged to dual pull members with a neutral position having a relative equal or zero force acting between the two pull members. Manipulation of the knob or slide in one direction away from the neutral position will exert force on one pull member, while manipulation of the slide or knob in the other direction away from the neutral position will exert force on the other pull member. The configuration of catheter body **4** associated with the neutral position may be a linear or a non-linear configuration.

Referring back to FIG. 3A, the proximal end of guide catheter **2** may have one or more parts **106**, **108** and **110**. These ports may communicate with conduit **6** or other conduits of multi-conduit embodiments of the invention. In some embodiments, one or more ports may be provided to obtain blood samples, for injection of intravenous fluids, radiographic or therapeutic agents, or for the attachment of a pressure transducer. One or more ports **106**, **108** and **110** may be configured with a hemostasis valve to reduce fluid or blood leakage, and/or a lock for resisting displacement of any components inserted into that port. In one embodiment, the lock is a releasable lock that can be released and re-engaged as needed. In some embodiments, the components used with a port may include one or more indicia along its length that may be used to identify the degree of insertion into guide catheter **2**.

In the specific embodiment depicted in FIG. 3A, port **106** associated with conduit **6**, may be configured for the insertion of a tunnel catheter or other instrument. In some embodiments, a tunnel catheter may be used in conjunction with guide catheter **2** to provide additional guidance beyond the distal end of guide catheter **2**. Providing a guidance pathway using both guide catheter **2** and a tunnel catheter may be easier to position at a target site or be easier to manufacture than a single guide catheter configured to traverse the entire guidance pathway.

For example, FIG. 12A depicts one exemplary use of a guide catheter **112** with a deformation zone **114**. Guide catheter **112** may be inserted from a peripheral vascular site and passed in a retrograde direction through the aorta A. As guide catheter **112** passes through the aortic valve, the steering mechanism of guide catheter **112** may be manipulated to bend toward the subvalvular region **116** adjacent the mitral valve leaflets MVL, as shown in FIG. 12B. Although

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a sharp turn may be formed in guide catheter 112 by providing a pathway from the aortic valve to the subvalvular region, instead of looping guide catheter 112 below the chordae tendinae or the apex of the left ventricle, deformation zone 18 permits controlled flexion that does not impinge or infold into the conduit provided in guide catheter.

In another variation, shown in FIG. 14A, the steerable catheter 4000 comprises a deformation region 4002 with a segment of the catheter body 4004 having a first layer segment 4006 and a second layer segment 4008 with a generally linear longitudinal interface 4010 therebetween. The first layer segment 4006 comprises a lower durometer material and the second layer segment 4008 comprises a higher durometer material. The catheter body 4004 may further comprise a proximal shaft 4012 and a distal shaft 4014 with respect to the deformation region 4002. The proximal shaft 4012 may comprise a tabular configuration with at least one inner lumen (not shown) that may be optionally lined with a coating. The proximal shaft 4012 may have a generally linear configuration, but in other variations, proximal shaft 4012 may have a non-linear configuration, including angled and curved sections or combinations thereof, such as the arch curve region 4018. The distal shaft 4014 may also have a linear or curved configuration, such as the valve curve region 4020 depicted in FIGS. 14B and 14C. Additional variations and methods of use for these and other deflectable guide catheters are described in U.S. Provisional Application No. 61/160,670 entitled "VISUALIZATION METHODS AND RELATED DEVICES AND KITS", filed Mar. 16, 2009, which is hereby incorporated by reference in its entirety. In some variations, the proximal shaft 4012 may comprise one or more reinforcement structures 4022, such as tubular or arcuate braiding or interweaving, circular loops, helical structures, or longitudinal supports). The reinforcement structure may comprise one or more metallic or non-metallic materials as described previously. In one example, the proximal shaft 4012 may comprise an outer layer of PEBAX 72 D, and the reinforcement structure 4022 may comprise a tubular stainless steel wire braid, which in turn may have an inner coating of PTFE. In the example of FIG. 14A, the distal shaft 4014 comprises a material having a durometer between the durometer of the first and second segments 4006 and 4008, but in other examples, the durometer may be generally equal to, less than or greater than the first and second segments 4006 and 4008, respectively. The distal shaft 4014 may also comprise an atraumatic tip 4024, which may comprise a material having lower durometer than the rest of the distal shaft 4014, or may be tapered or otherwise shaped to be more flexible or deformable. The distal shaft 4014 may comprise a linear or non-linear configuration, and may be oriented in the same or a different plane with respect to the deformation region 4002 and/or proximal shaft 4012, as shown in FIG. 14D.

Referring to FIG. 14B, the proximal shaft 4012 may further comprise a pull lumen 4026 and a pull member 4028 within the wall of proximal shaft 4012. The pull lumen 4026 and/or pull member 4028 may also be coated with a reduced friction coating, such as PTFE. In further variations, the pull lumen 4026 may be reinforced with a material such as polyimide. The pull member 4028 may comprise any of a variety of materials, including but not limited to stainless steel, nylon, polyimide, and the like. The pull lumen 4026 and/or pull member 4028 may terminate within the deformation region 4002 or the distal shaft 4014. To facilitate the exertion of force in the distal shaft 4014 of the catheter body 4004, the pull member 4028 may comprise a distal pull

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structure 4030, such as a ring-like structure embedded in the distal shaft 4014. As noted elsewhere, the pull member 4028 may comprise any of a variety of materials and structures sufficient to transmit longitudinal forces along a length of the catheter body 4004. The pull member 4028 and the distal pull structure 4030 may be metallic, non-metallic or a combination thereof, including but not limited to stainless steel, Nitinol, nylon or other polymeric material. In some variations, the pull member 4028 may be coated, for example, to facilitate sliding in the pull lumen 4026, such as PTFE.

FIG. 14D depicts the proximal end 4030 of the steerable catheter 4000, comprising a rotatable knob 4032, a guide hub interface 4034, a hemostasis valve 4036 and a stopcock 4038. The knob 4032 may be configured to adjust the tension of the pull member 4028 by knob rotation, but in other variations, tension adjustment may occur by pulling the knob. Referring to FIG. 15E, the pull member 4028 may be attached to a hypotube 4040 by crimping, welding, adhesives or the like. The hypotube 4040 may be attached to a key structure 4042 which forms a complementary interfit with the knob 4032 to axially displace the pull member 4028 while permitting relative rotational movement between the knob 4032 and the key structure 4042. The key structure 4042 may also be axially secured to the knob 4032 using a screw 4044 or other attachment structure which permits relative rotational movement. In other variations, the knob may be configured to transmit rotational movement to the pull member.

An inner sleeve 4046 with an outer threaded surface 4048 may be attached to the base 4050 of the steering assembly. The outer threaded surface 4048 may interface with the inner threaded surface 4052 of the knob 4032. In some variations, to permit axial movement while restrict rotational movement of the pull member 4028, the hypotube 4040 or the key structure 4042 may be configured with a non-circular shape and/or one or more side protrusions which may resist rotational movement along an inner lumen 4054 of the inner sleeve 4046. For example, FIG. 14E depicts the inner lumen 4054 comprising an elongate groove 5056 which accommodates axial movement of the set screws 5058 attached to and protruding from the key structure 4042 while restricting rotational displacement of the screws 5058.

To reduce the risk of blood or fluid leakage from the catheter 4000 during a procedure, the proximal end 4030 may further comprise a hemostasis valve or seal 5060 through which instruments may be inserted or withdrawn. The hemostatic seal may comprise any of a variety of configurations known in the art. In some examples, the hemostatic seal may comprise one or more slits on a septum or sealing member which forms one or more seal flaps. Upon insertion of an instrument or device through the sealing member, the seal flaps deform or deflect to permit passage of the device while exerting force around a perimeter of the device to substantially resist passage of fluid or gas through the sealing member. Referring to FIGS. 15A to 15C, in some examples, the sealing member 4100 has a seal opening 4102 comprising at least one non-linear slit 4104a-d with respect to the seal face 4106 or a transverse plane of the seal axis 4108. In the depicted example, the sealing opening 4102 comprises four arcuate or spiral-shaped slits 4104a-d arranged about the seal axis 4108. Each of the slits 4104a-d has the same relative shape and size as the other slits 4104a-d and uniformly spaced around the axis 4108, but in other examples, a different number of slits may be provided, one or more slits may have a different size or shape, the slits may be non-uniformly spaced or non-symmetrically

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arranged, and/or may intersect at location different from the center of the seal face **4106**. In FIG. **16**, for example, the sealing member **4130** comprises a plurality of multi-angled slits **4132a-d**. Referring back to FIG. **14D**, the hemostasis valve **4036** and the stopcock **4038** may be detached from the guide hub **4034** to permit direct insertion of instruments into the catheter **4000**, or to attach other configurations of hemostasis seals, valves, connectors, sensors and the like.

Referring back to FIGS. **15A** to **15C**, the slits **4104a-d** may have a generally orthogonal orientation through the seal face **4106**, or may be angled or skewed. In some examples, the slits **4104a-d** may be generally angled with respect to the seal face **4106** in the range of about 5 degrees to about 85 degrees, in some configurations about 10 degrees to about 60 degrees, and in other configurations about 20 degrees to about 45 degrees. The seal face **4106** or the seal member **4100** may comprise any of a variety of elastic or flexible materials, including any of a variety of silicones such as NuSil Med-4035, Med-4820, and MED50-5338, may have a durometer in the range of about 20 to about 80, in some examples about 15 to about 60, and in other examples about 20 to about 40. The thickness **4110** of the seal face **4106** may be in the range of about 0.01" to about 0.1", in some examples about 0.02" to about 0.05", and in other examples about 0.025" to about 0.03". As illustrated in FIG. **15B**, the seal face **4106** may be raised or offset from the body **4112** of the sealing member **4100**. The raised distance **4114** of raised seal face **4106** may be in the range of about 0.01" to about 0.2", in some configurations about 0.02" to about 0.1" and in other configurations about 0.04" to about 0.06".

The body **4112** may comprise a lumen **4116** in communication with the sealing opening **4102**. The lumen **4116** may have a uniform or non-uniform diameter, cross-sectional area and/or cross-sectional shape. Lumens with non-uniform diameters may taper toward or away from the seal opening **4102**, and the taper may be linear or non-linear. In some examples, the lumen **4116** may have an average diameter **4118** in the range of about 0.05" to about 0.5" or more, in some configurations about 0.1" to about 0.3", and in other configurations about 0.15" to about 0.2". The lumen **4116** may have a length **4120** anywhere in the range of about 0.1" to about 1" or more, in some configuration about 0.2" to about 0.5", and in other configurations about 0.25" to about 0.4". The body **4112** may have any of a variety of shapes, including cylindrical, frustoconical, box-like or other shapes, and may be coupled to the guide tunnel by a frame or housing.

As illustrated in FIGS. **13A** to **13E**, in one embodiment, guide catheter **112** is used to access the subvalvular region **116** for delivery of a cinchable implant. After passing a guidewire **118** through guide catheter **112** and along subvalvular region **116**, a multi-window tunnel catheter **120** is passed down guidewire **118**. In one embodiment, tunnel catheter **120** a releasable multi-window tunnel catheter as described in one or more embodiments of U.S. Pat. Appl. Ser. No. 61/026,697, entitled "MULTI-WINDOW GUIDE TUNNEL" filed on Feb. 6, 2008, which is herein incorporated by reference in its entirety. After guidewire **118** is removed from tunnel catheter **120**, a delivery catheter (not shown) carrying one or more deployable anchors **122** coupled to a tether is secured to the subvalvular region **116**. Embodiments of various devices usable with embodiments of the invention are described in U.S. patent application Ser. Nos. 10/656,797, 10/741,130, 10/792,681, 10/900,980, 10/901,555, 11/201,949, 11/202,474, 11/232,190, 11/255, 400, 11/270,034 and 11/583,627, which are incorporated by reference in their entirety.

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In other embodiments, any of a variety of catheters and intraluminal instruments may be configured with one or more deformation zones. In addition to performing cinching of the subvalvular region about the mitral valve, these catheters and instruments may be used for other therapeutic and diagnostic procedures, including but not limited to access other cardiac valves (e.g. tricuspid valve, pulmonary valve and aortic valve), access to the coronary vasculatures, including the coronary arteries and coronary venous vasculature, including the coronary sinus, transseptal, transapical and other transmyocardial procedures, electrophysiological procedures, implantation of cardiac rhythm management devices, genitourinary procedures, gastrointestinal procedures including access to the hepatobiliary tree, cerebrovascular procedures including implantation of vascular coils, and others.

While this invention has been particularly shown and described with references to embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention. For all of the embodiments described above, the steps of the methods need not be performed sequentially.

What is claimed is:

1. A method for accessing a cardiac region of a patient, comprising:

advancing a guide catheter from a peripheral vascular site in a retrograde direction through an aorta into a left ventricle, the guide catheter comprising a tubular body comprising a proximal section and a distal section, the distal section comprising a deformation zone, a curved pre-deformation section proximal to the deformation zone and a curved post-deformation section distal to the deformation zone, wherein the deformation zone has a proximal end, a distal end, a longitudinal length and a longitudinal axis therebetween, a first constricting portion, a second constricting portion and a compressible portion in alternating configuration with the first and second constricting portions along the longitudinal axis, wherein the first and second constricting portions have a higher hardness and the compressible portion has a lower hardness and wherein the guide catheter further comprises a pull member coupled to a pull structure that is located in the post-deformation section; steering the guide catheter into a subvalvular region adjacent mitral valve leaflets by pulling the pull member to bend the catheter such that the first and second constricting portions compress the compressible portion therebetween.

2. The method of claim 1, wherein the proximal section has a pre-configured curve.

3. The method of claim 1, wherein the pull structure comprises a ring-like structure.

4. The method of claim 3, wherein a proximal end of the pull member is coupled to a rotating knob.

5. The method of claim 3, wherein a proximal end of the pull member is coupled to a lever.

6. The method of claim 3, wherein a proximal end of the pull member is coupled to a bias member.

7. The method of claim 1, further comprising passing an instrument down a conduit of the guide catheter.

8. The method of claim 7, wherein the instrument is a multi-window tunnel catheter.

9. The method of claim 7, wherein the instrument is guidewire.

10. The method of claim 1, wherein advancing the guide catheter comprises passing the guide catheter through an

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aortic valve to the left ventricle, and steering the guide catheter into the subvalvular region from the aortic valve comprises bending the deformation zone to prevent looping of the guide catheter below chordae tendinae of the left ventricle.

11. The method of claim 1, wherein the deformation zone is at an angle with respect to the pre-deformation section.

12. The method of claim 11, wherein the angle is from about 0 degrees to about 345 degrees.

13. The method of claim 1, wherein the compressible portion is located between the first constricting portion and the second constricting portion.

14. The method of claim 1, wherein the guide catheter further comprises a reinforcement structure surrounding the tubular body.

15. The method of claim 14, wherein the reinforcement structure comprises a tubular braid.

16. The method of claim 1, wherein the compressible portion of the deformation zone is a first compressible portion and wherein the deformation zone further comprises a second compressible portion and a third constricting portion, wherein the second compressible portion is in alternating configuration with the second and third constricting portion along the longitudinal axis of the deformation zone, wherein the second compressible portion has a lower hardness and the third constricting portion has a higher hardness, and wherein bending the catheter causes the second and third constricting portions to compress the second compressible portion.

17. A method for accessing a cardiac region of a patient, comprising:

advancing a guide catheter from a peripheral vascular site in a retrograde direction through an aorta into a left

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ventricle, the guide catheter comprising a tubular body comprising a proximal section and a distal section, the distal section comprising a deformation zone, a curved pre-deformation section proximal to the deformation zone and a curved post-deformation section distal to the deformation zone, wherein the deformation zone has a proximal end, a distal end, a longitudinal length and a longitudinal axis therebetween, a first constricting portion, a second constricting portion and a compressible portion in alternating configuration with the first and second constricting portions along the longitudinal axis, wherein the first and second constricting portions have a higher hardness and the compressible portion has a lower hardness and wherein the guide catheter further comprises a pull member coupled to a pull structure that is located in the post-deformation section; passing the guide catheter through a cardiac valve orifice; and

steering the guide catheter into a subvalvular region adjacent the cardiac valve orifice by pulling the pull member to bend the catheter such that the first and second constricting portions compress the compressible portion therebetween.

18. The method of claim 17, wherein the cardiac valve orifice is an aortic valve orifice.

19. The method of claim 17, wherein the cardiac valve orifice is a mitral valve orifice.

20. The method of claim 17, further comprising passing an instrument down a conduit of the guide catheter.

21. The method of claim 17, wherein the instrument is a multi-window tunnel catheter.

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